K111848

OCT - 5 2011

510(k) Summary of Safety and Effectiveness

Proprietary Name:	Exeter X3 RimFit Acetabular Cup
Common Name:	Hip prosthesis
Classification Name and Reference:	Hip joint metal/polymer semi-constrained cemented prosthesis 21 CFR §888.3350
Regulatory Class:	Class II
Product Codes:	87 JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented
For Information contact:	Estela Celi, Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6461 Fax: (201) 831-3461
Date Prepared:	August 16, 2011

Description:
This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the new Exeter X3 RimFit Acetabular Cup manufactured from a modified sequentially crosslinked and annealed Ultra High Molecular Weight Polyethylene (UHMWPE) material. The proprietary name of the subject polyethylene material is X3® UHMWPE.

Intended Use:
The Exeter X3 RimFit Acetabular Cup is a sterile, single-use device intended for use in primary and revision total hip arthroplasty to alleviate pain and restore function. This device is intended to be used with any currently available compatible Howmedica Osteonics' acetabular components. Compatibility with the femoral heads includes: V40 and C-Taper (LFIT™, CoCr, Biolox delta, Alumina, and Orthinox).

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Indications:
The indications for use of total hip replacement prostheses include:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques, such as cementless fixation, as indicated by deficiencies of the acetabulum

Stryker's Exeter X3 RimFit Acetabular Cup is intended for cemented use only.

Summary of Technologies:
Device comparison showed that the proposed device is substantially equivalent in intended, use, materials and performance characteristics to the predicate device. The predicate devices used for comparison to the proposed device are the following; The Trident All Poly Cup, Trident X3 Acetabular Insert, Exeter Hip System With V40 Taper and the Opera Cup (Smith & Nephew).

Non-Clinical Testing:
Non-clinical laboratory testing was performed for the acetabular cup to determine substantial equivalence. Non-clinical testing was provided as outlined in the FDA Guidance Document entitled "Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis (April 30, 2002)". Lever-out post fatigue testing was conducted on the worst-case size determined by Finite Element Analysis. Pull-out testing was performed on the cement spacers in order to evaluate their mechanical strength. The testing demonstrated that the Exeter X3 RimFit Acetabular Cup is substantially equivalent to devices currently cleared for marketing.

Clinical Testing: Clinical testing was not required for this submission.

Conclusion: The Exeter X3 RimFit Acetabular Cup is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corporation
% Ms. Estela Celi
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

OCT - 5 2011

Re: K111848
Trade/Device Name: X3 RimFit Acetabular Cup
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: August 16, 2011
Received: August 17, 2011

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111848

Device Name: Exeter X3 RimFit Acetabular Cup

Indications for Use:

The indications for use of the total hip arthoplasty include:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques, such as cementless fixation, as indicated by deficiencies of the acetabulum

Stryker's Exeter X3 RimFit Acetabular Cup is intended for cemented use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111848